

REMARKS

Claims 68, 71-72, 75-80, 82-83, 88-96, 108-109, 111, 115-116, 119, 121, 123 and 125 are presently pending and under examination in the case. Claims 70, 85-87, 117-118, 120, 122, 124 and 126 have been canceled herein without prejudice. Claim 68 has been amended to recite the active substance of Claim 87. The remainder of the claims have been amended to correct claim dependencies. No new matter is added by the amendments.

Rejection of claims under 35 U.S.C. §103

The Office Action has maintained the rejections of Claims 68, 70-72, 75-80, 82-83, 85-86, 91-92, 95-96, 108-109, 111, 119-126 over Nemoto (JP 3-240729) in view of Klioze (US Patent 2,887,439)

As discussed above, Applicants have herein incorporated the active substance of Claim 87. As such, Applicants contend that the rejection over Nemoto (JP 3-240729) in view of Klioze (US Patent 2,887,439) is moot.

The Office Action has further maintained the rejections of Claims 87-90, 93-94 and 115-118 over Nemoto (JP 3-240729) in view of Klioze (US Patent 2,887,439) and over Nemoto in view of Klioze and Penkler (US Patent 5,854,226). Applicants respectfully traverse.

The Office Action asserts that Nemoto teaches all of the elements of the invention except as described. The Office Action states that Nemoto does not expressly teach a mean particle size of at most 250 micrometers. The Office Action relies on Klioze to provide this limitation. Specifically, the Office Action asserts that Klioze teaches a rapidly disintegrating tablet comprising granules that are between 149 and 840 micrometers. The Office Action further states that Nemoto and Klioze do not expressly teach lornoxicam as an active substance. The Office Action relies on Penkler to provide this limitation.

Specifically, the Office Action asserts that Penkler teaches a pharmaceutical composition comprising lornoxicam and an alkaline earth metal bicarbonate.

That is, the Office Action asserts that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to make an oral granule preparation containing an antacid and an oxicam drug, as suggested by Nemoto, reduce the granule size to a range between 149 micrometers and 840 micrometers, as taught by Klioze, and use lornoxicam as the drug along with an alkaline earth metal bicarbonate, as suggested by Penkler, and produce the instant invention."

Applicants respectfully disagree.

As an initial comment, the Office Action points to the results of Nemoto from solubility tests in artificial gastric juice to demonstrate that the compositions made by the methods of Nemoto have the same properties as the compositions of the instant claims. Applicants note that Nemoto provides compositions comprising chlortenoxicam with solubility test results and does not provide compositions comprising lornoxicam or a pharmaceutically acceptable salt, complex or prodrug thereof. As discussed in prior responses, the Nemoto reference was cited in the prosecution of the parent application as noted above. A Declaration was filed by one of the inventors Poul Bertelsen in which the dissolution of a composition, comprising lornoxicam and prepared according to the teachings of Nemoto, was tested using the method required in the claims of the instant invention. (A copy of the Declaration is submitted herewith as Exhibit A for the Examiner's convenience). The results are provided in Appendix A of the Declaration. After 1 hour, the composition, prepared according to the teachings of Nemoto and comprising a 1:5 ratio of lornoxicam to antacid, was found to release only 37.8% in 0.07N HCl. Therefore, the amount released after 20 minutes must have been less than 50% as required by the instant claims. As the **composition comprising lornoxicam and prepared according to Nemoto does not meet the dissolution requirement of the claim**, Nemoto cannot render the instant claim obvious.

Applicants have shown that the methods described by Nemoto (i.e. conventional granulation) can not produce compositions comprising lornoxicam which would achieve the dissolution requirements of the claimed invention. As such, Applicants contend that one of ordinary skill in the art would not find the instant claims obvious in light of the combination of Nemoto, Klioze and Penkler.

CONCLUSION

In view of the foregoing, reconsideration and withdrawal of all rejections, allowance of the instant application with all pending claims, and prompt issuance of a Notice of Allowance are earnestly solicited. If a telephone conversation with Applicants' representatives would help expedite the prosecution of the above-identified application, Applicant invites the Examiner to call Applicant's representatives at the telephone number below.

Please charge any required fee or credit any overpayment to Deposit Account No. 04-1105, under Order No. 55682CON(71432).

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Respectfully submitted,

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